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Board of Registration in Pharmacy

Policy 2022-07: Automated Pharmacy Systems

The Board of Registration in Pharmacy ("Board") authorizes this policy to facilitate patient access to filled Schedule IV through VI prescriptions from automated pharmacy systems. In the case of a licensed healthcare facility, approval for use and placement must be obtained from the facility's licensing body (e.g., Bureau of Health Care Safety and Quality).

Automated Pharmacy System ("APS") means an automated patient-facing device that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications. The APS releases patient medications after correct patient identifiers are provided. The APS must have a method to collect and provide all transaction information.

NOTE: If approved by the Board, an APS meeting all the requirements of this policy is considered an extension of the pharmacy's licensed area whether its location is contiguous or non-contiguous to the pharmacy.

I. A pharmacy may dispense Schedule IV through VI controlled substances from an APS to a patient or a patient's agent during or after pharmacy hours of operation provided the following requirements are met:

A. The APS is located within the same building as the pharmacy with the same physical address.

B. The APS is secured against or within a wall or floor in a manner that prevents unauthorized access and removal.

C. The location and APS are monitored by continuous, recordable video surveillance.

D. A pharmacy may not stock medications in an APS that require refrigeration or reconstitution.

E. The APS utilizes industry standard technological verification such as bar code verification, radio frequency identification, or other similar process, to ensure the correct medication is dispensed to the correct patient.

F. If filled prescriptions for Schedule IV, V, or Schedule VI additional drugs (i.e., gabapentin) will be stored in the APS for patient pickup:
    1. the identity of the person to whom the medication is released must be collected and maintained. In addition, all reporting requirements of the Prescription Monitoring Program ("PMP") must be met; and
    2. the DEA must be consulted for any additional requirements.
G. The APS or the pharmacy that operates the APS maintains an electronic audit trail of all APS transactions.
H. The pharmacy allows the patient to choose whether or not to use an APS.
I. In the case of new or changed therapy for the patient, the pharmacy must provide the offer to counsel.
J. The pharmacy provides the means and opportunity for a pharmacist consultation during the pharmacy's usual hours of operation.
K. Prior to use, Board-licensed pharmacies must submit a written request for approval with details including, but not limited to:
    1. type of APS (e.g., brand, model, etc.);
    2. hours the APS will be available for use;
    3. schedules of controlled substances (limited to Schedule IV through VI);
    4. security measures; and
    5. completed Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage.

II. A pharmacy utilizing an APS shall maintain policies and procedures pertaining to the APS that include:

A. operation and maintenance;
B. security;
C. controlled substances accountability;
D. quality assurance;
E. stocking and return activities; and
F. patient confidentiality.

Please direct any questions to: Pharmacy.Admin@mass.gov